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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,397	06/25/2003	James A. Peterson	2992.10US04	4852

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/603,397	Applicant(s) PETERSON ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/03, 12/12/03, 10/25/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because figs. 1-9 and 16-27 are hand drawn. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

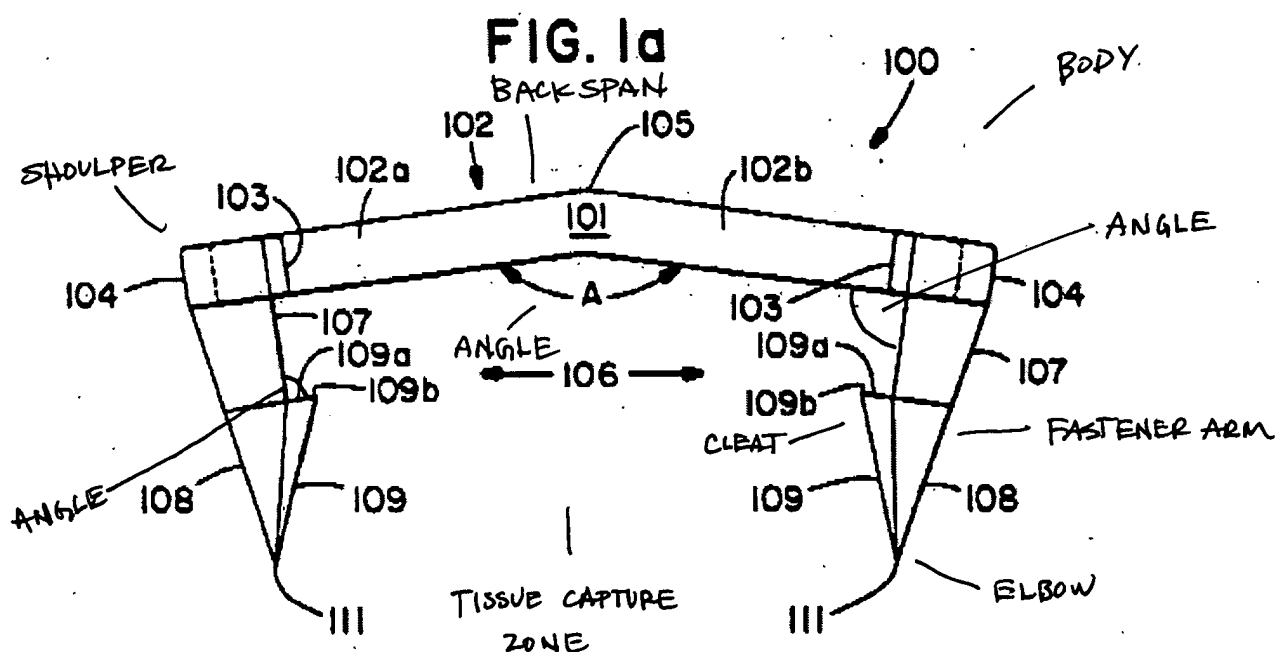
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-5, 8, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Green. 5089009.

3. Green teaches a bioabsorbable fastener comprising: a fastener body formed of a generally bioabsorbable polymer material (col. 2, lines 32-35) and defining a initial tissue capture zone, the fastener body including: a pair of fastener arms; a cleat operably joined to each fastener arm at an elbow portion and projecting backward into the initial capture zone with an internal elbow angle defined between the cleat and the fastener arm; a durably tissue retention zone of each fastener arm defined between the cleat and the fastener arm and having an apex at the elbow portion; a maximum insertion width of each fastener arm defined between the outermost surfaces of the cleat and the fastener arm; a backspan operably joined to each fastener arm at a shoulder portion with corresponding internal shoulder angles defined between the backspan and each fastener arm and an internal midspan angle defined between a midpoint of the backspan and the apex of each durable tissue retention zone, the Applicant is silent as to the width of the pierced opening and therefor the device of Green meets the limitation of wherein the elbow portion and the internal elbow angle of each fastener arm are constructed with the maximum insertion width being greater than a width of the corresponding pierced opening; wherein the shoulder portions and the internal shoulder angles are constructed so as to capture wound tissue within the initial capture zone during deployment of the fastener and then dynamically reform in response to lateral stresses applied by the wound tissue after deployment such that a sum of the internal elbow angles and the internal midspan angle remains less than 360 degrees (col. 3, line

49-col. 4, line 2); wherein the initial tissue capture zone is defined by a generally planar cross section defined by a coplanar orientation of a centerline of each of the pair of fastener arms and the backspan; wherein the shoulder portions and the internal shoulder angles are constructed so as to generally maintain a shape of the initial tissue capture zone during deployment of the fastener and not dynamically reform in response to lateral stresses applied by the wound after deployment for an initial period of time less than the minimum degradation period (col. 3, line 49-col. 4, line 2).



4. Claims 3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Green.
5. Green teaches the fastener of claim 1 formed generally of a bioabsorbable material. Green is silent in regards to the degradation period. However, it is well known in the art of surgical staples to construct a staple out of bioabsorbable material with the

claimed degradation periods (as evidenced by Person et al. 5593423). Therefore, it would have been obvious to one having ordinary skill in the art to use the claimed degradation periods to allow for healing and easy removal.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green.

8. As to claim 6, Green teaches the fastener of claim 1. It should be noted that Green fails to teach wherein the internal elbow angles are constructed in a range between 15-70 degrees and the internal shoulder angles are constructed in a range between 70 and 110 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. As to claim 7, Green teaches the fastener of claim 1. It should be noted that Green fails to teach wherein the internal elbow angles are less than the internal shoulder angles. However, it would have been obvious to one having ordinary skill in

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the art at the time the invention was made to use the angle as recited in the claim because the particulars of the angle are a mere design choice obtained through routine observation and experimentation. Furthermore, it is well known in the art of staples to have internal elbow angles that are less than the internal shoulder angles to staple retention purposes (as evidenced by Place 2283814 and Schneider 3757629).

Allowable Subject Matter

10. Claims 10-12 are allowable over the prior art of record.

11. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of a dynamic bioabsorbable staple for use with a wound in living tissue having opposed sides, the staple comprising: a staple body, a pair of staple arms joined at a shoulder portion by a backspan, each arm further including an elbow portion having an inwardly projection cleat, each shoulder portion including an interior shoulder angle generally defined by the backspan and the staple arm, the shoulder portion constructed so that the interior shoulder angle is between 70-100 degrees in a first position at an insertion time, the interior shoulder angle transitioning to between 120-180 degrees in a second deformed position at a second time subsequent to the insertion time in response to lateral forces naturally exerted by the opposed sides of the wound.

12. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM


GLENN K. DAWSON
PRIMARY EXAMINER